

EXHIBIT G



**DEPARTMENT OF HEALTH AND HUMAN
SERVICES**

Office of the General Counsel
Centers for Medicare &
Medicaid Services Division

330 Independence Ave.,
S.W.
Room 5309 Wilbur J. Cohen
Building
Washington, D.C. 20201

September 27, 2018

Jeffrey Coopersmith
Davis Wright Tremaine LLP
505 Montgomery Street, Suite 800
San Francisco, CA 94111

Dear Mr. Coopersmith,

This letter responds to the Rule 45 discovery subpoena that you served on behalf of Ramesh Balwani, the defendant in *SEC v. Ramesh "Sunny" Balwani*, No. 18-cv-01603 (N.D. Cal.) on the U.S. Department of Health & Human Services ("HHS"), Office of the General Counsel ("OGC"), which was received by the OGC on or about September 14, 2018.

We write to provide you with a brief statement of our objections to your September 14, 2018 subpoena. Because our review of the subpoena continues, we reserve the right to supplement these objections in the future. We also specifically reserve and do not waive other objections that may be applicable in discovery or at trial.

First, we object to the subpoena as vague and ambiguous, overly broad and unduly burdensome. For example, the definition of "YOU," "YOUR," and "YOURS" is vague and ambiguous, overly broad and unduly burdensome to the extent it includes parties beyond CMS and CMS contractors. The definitions of "LAB OR LAB ASSOCIATION" and "HEALTH CARE INDUSTRY" and the document request that use those terms (Nos. 13 and 15) are also vague and ambiguous, overly broad and unduly burdensome. The definition of "LAB OR LAB ASSOCIATION" includes all clinical laboratories in existence, all industry or trade associations, and any persons or entities in any way affiliated or associated with such clinical laboratories or industry or trade associations. The definition of "HEALTH CARE INDUSTRY" is defined to refer to the entire health care industry and any person or entity associated with anyone in the health care industry.

Second, we object to Instruction No. 21 to the extent that it assumes that some degree of document search is always possible, notwithstanding an objection based on vagueness, ambiguity, overbreadth and/or undue burden.

Third, we object to Instruction No. 23 that purports to require the production of a privilege log for those document requests where we have objected in full and for document requests that seek privileged information.

Fourth, we object to the subpoena to the extent it requests documents that we believe are already in the possession of the Defendant, or could easily be obtained through other means. For example, the subpoena seeks communications about meetings and calls CMS had with Theranos, Ms. Holmes, or Mr. Balwani. The Defendant should already have access to communications, meetings, and calls that his company had with CMS. The subpoena also seeks documents and communications relating to Theranos's compliance with CLIA regulations and any CMS Form 2567 and/or Plan of Correction relating to Theranos. Any responsive documents should already be in the possession of the Defendant, except for internal deliberative CMS communications that are protected by the deliberative process privilege.

Fifth, we object to the extent the subpoena asks for documents and communications relating to Theranos's compliance with state law because those documents are not within the custody and control of CMS.

Sixth, we object to the subpoena to the extent it requires HHS to draw legal conclusions or otherwise seeks to impose upon HHS any requirements beyond those established by the Federal Rules of Civil Procedure or the Local Rules of the United States District Court for the Northern District of California.

Seventh, we object to the subpoena to the extent that it seeks information or documents protected from disclosure by privilege or doctrine, including the attorney-client privilege, the investigative file privilege, the work product privilege, the deliberative process privilege, the law enforcement privilege, or any other applicable basis for invoking privilege. *See* Fed. R. Civ. P. 45(c)(3)(A)(iii). For example, the subpoena seeks internal CMS communications about the 2567 and the Plan of Correction that are predecisional and deliberative.

Eighth, we object to the subpoena to the extent it seeks confidential information on individual Medicare beneficiaries that is protected from disclosure by Federal law, specifically section 1106 of the Social Security Act, 42 U.S.C. § 1306, and the Privacy Act of 1974, 5 U.S.C. § 552a. *See also* 42 C.F.R. § 401.105; 45 C.F.R. § 5b.9 and § 164.512(e).

Finally, we object to the subpoena on the ground that the time provided to produce documents is unreasonable. *See* Fed. R. Civ. P. 45(c)(3)(A)(i). The subpoena requests 8 years of data on a variety of overly broad topics. Given the time needed to identify, collect, and process the data responsive to this extremely broad subpoena, directing CMS to respond by October 15, 2018 is unreasonable.

We are committed to working with you to resolve these concerns and produce responsive data in a manner consistent with federal law, regulations, and procedure, without subjecting the Department to an unreasonable burden. Please contact me directly at Lindsay.Turner@hhs.gov to set up a call to discuss this matter further.

Sincerely,

A handwritten signature in black ink, appearing to read "Lindsay Turner", with a long horizontal flourish extending to the right.

Lindsay Turner
Office of the General Counsel-CMS Division
U.S. Department of Health & Human Services
(202) 205-5867
Lindsay.Turner@hhs.gov

cc: Sara Winslow, Chief, Civil Division, U.S. Attorney's Office, Northern District of California